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EXAMINER

STRZELECKA, T

ART UNIT

PAPER NUMBER

1656

DATE MAILED: 05/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/404,520

Applicant(s)

CAO ET AL.

Examiner

Teresa E Strzelecka

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29,30 and 47-58 is/are pending in the application.
- 4a) Of the above claim(s) 30 and 47-54 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 57 and 58 is/are allowed.
- 6) ☒ Claim(s) 29,55 and 56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of SEQ ID NO. 16207 in Paper No. 11 is acknowledged.

The traversal is on the ground that a restriction to a single nucleotide sequence prevents the claimed invention of at least 100 sequences from being examined. This is not found persuasive because MPEP 803.04 states:

MPEP 803.04

Restriction - Nucleotide Sequences

By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant . . . to elect that invention to which his claim shall be restricted." 37 CFR 1.142(a). See also 37 CFR 1.141(a).

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Nevertheless, to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided sua sponte to partially waive the requirements of 37 CFR 1.141 et seq. and permit a reasonable number of such nucleotide sequences to be claimed in a single application. See Examination of Patent Applications Containing Nucleotide Sequences, 1192 O.G. 68 (November 19, 1996).

It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction. In addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined. Furthermore, nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together.

Because of considerable search burden on the Patent Office due to a large number of applications which require sequence searches, it was determined that a single oligonucleotide sequence will be searched and examined for each application.

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The requirement is still deemed proper and is therefore made FINAL.

2. Claims 30, 47-54 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected SEQ ID Nos., there being no allowable generic or linking claim. Claims 29, 55-58 will be examined to the extent that they read on SEQ ID NO: 16207. Applicant timely traversed the restriction (election) requirement in Paper No. 11.

Specification

3. The disclosure is objected to because of the following informalities:

A) Page 44, lines 2 and 9; page 45, line 14: active internet links (should not start with "http").

B) Page 52, lines 6 and 7: primer sequences without SEQ ID NOS.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 29, 55 and 56 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 29, 55 and 56 are drawn to computer readable media having recorded thereon SEQ ID NO: 16207.

The following are excerpts from "The Examination Guidelines for Computer-Related Inventions", which describes subject matter related to descriptive material recorded on a computer readable medium.(see www.uspto.gov/web/offices/com/hearings/software/analysis/computer.html) (Section IV, B1) Non-Statutory Subject Matter

Claims to computer-related inventions that are clearly non-statutory fall into the same general categories as non-statutory claims in other arts, namely natural phenomena such as

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magnetism, and abstract ideas or laws of nature which constitute "descriptive material." Descriptive material can be characterized as either "functional descriptive material" or "non-functional descriptive material." In this context, "functional descriptive material" consists of data structures and computer programs which impart functionality when encoded on a computer-readable medium. **"Non-functional descriptive material" includes but is not limited to music, literary works and a compilation or mere arrangement of data.**

Both types of "descriptive material" are non-statutory when claimed as descriptive material *per se*. When functional descriptive material is recorded on some computer-readable medium it becomes structurally and functionally interrelated to the medium and will be statutory in most cases. **When non-functional descriptive material is recorded on some computer-readable medium, it is not structurally and functionally interrelated to the medium but is merely carried by the medium. Merely claiming non-functional descriptive material stored in a computer-readable medium does not make it statutory. Such a result would exalt form over substance. Thus, non-statutory music does not become statutory by merely recording it on a compact disk.** Protection for this type of work is provided under the copyright law.

(Section IV, B1(b)) Non-Functional Descriptive Material

Descriptive material that cannot exhibit any functional interrelationship with the way in which computing processes are performed does not constitute a statutory process, machine, manufacture or composition of matter and should be rejected under § 101. Thus, Office personnel should consider the claimed invention as a whole to determine whether the necessary functional interrelationship is provided.

Where certain types of descriptive material, such as music, literature, art, photographs and mere arrangements or compilations of facts or data, are merely stored so as to be read or output by a computer without creating any functional interrelationship, either as part of the stored data or as part of the computing processes performed by the computer, then such descriptive material alone does not impart functionality either to the data as so structured, or to the computer. Such "descriptive material" is not a process, machine, manufacture or composition of matter.

The policy that precludes the patenting of non-functional descriptive material would be easily frustrated if the same descriptive material could be patented when claimed as an article of manufacture. For example, music is commonly sold to consumers in the format of a compact disc. In such cases, the known compact disc acts as nothing more than a carrier for non-functional descriptive material. **The purely non-functional descriptive material cannot alone provide the practical application for the manufacture.**

In the instant application, the claims are drawn to non-functional descriptive matter, i.e. a mere arrangement of data (i.e. SEQ ID NO: 16207), recorded on a computer readable medium to be read or output by a computer. The claims fails to create any functional interrelationship with any

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computing process performed by a computer. The claims are not drawn a process, machine, manufacture or composition of matter, and therefore, fails to comply with 35 U.S.C. 101.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 55 and 56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 55 and 56 contain a limitation "...computer readable medium....adapted for homology searching...". It is unclear what is the meaning of "adapted for homology searching", since it is not defined in the disclosure.

7. Claims 57 and 58 are allowable. No references were found teaching or suggesting SEQ ID NO:16207.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E Strzelecka whose telephone number is (703) 306-5877. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-3014 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

TS
May 21, 2001

TS

Kenneth R. Horlick, Ph.D.
KENNETH R. HORLICK
PRIMARY EXAMINER 5/21/01
GROUP 1600